

Application No. 10/761,596  
Amendment dated January 24, 2005  
Reply to Office Action of September 22, 2004

### **REMARKS**

Applicant respectfully requests entry of the Amendment and reconsideration of the claims. Claims 9 to 11 have been amended to further clarify the invention. Claims 12-13 stand as previously submitted. Claims 14-16 are new. After entry of the Amendment, claims 9-16 will be pending.

Applicant submits the new claims are supported throughout the specification as originally filed, see for example the last paragraph of page 8 and Examples 1 and 2, and raise no issues of new matter

### **Claim Objections**

The Examiner objected to informalities in. As suggested by the Examiner, Claim 11 has been amended to delete the term "the" before "symptoms." Withdrawal of the rejection is respectfully requested

### **Anticipation**

Claim 10 was rejected under 35 U.S.C. § 102(b) as anticipated by US 5,320,862 (Klokkers-Bethke et al.) or US 5,580,566 (Veronesi et al.). Applicant respectfully traverses the rejection.

To anticipate a claim, each and every element of the claim must be described, either expressly or inherently, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Claim 10 is directed to compositions comprising a nitric oxide agonist, wherein the composition is structurally modified to preferentially release nitric oxide in the liver. Klokkers-Bethke et al. and Veronesi et al. disclose compositions that contain a nitric oxide agonist. Neither of the references, however, discloses compositions that are structurally modified to preferentially release nitric oxide in the liver. Neither Klokkers-Bethke et al. nor Veronesi et al. teach or suggest their disclosed compositions are capable of preferentially releasing nitric oxide in the liver. Therefore, neither of the references cited by the Examiner teach every element of Applicant's claim.

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The references cited by the Examiner do not anticipate Applicant's claim. Neither reference teaches every element of Applicant's claim. Accordingly, Applicants respectfully request withdrawal of the rejection under § 102(b).

Claim 9 was rejected under 35 U.S.C. § 102(e) as anticipated by US 6,165,976 (Adams et al.), US 6,171,232 (Papandreu et al.), or US 5,958,427 (Salzman et al.). Applicant respectfully traverses the rejection.

Claim 9 is directed to compositions comprising a nitric oxide donor, wherein the composition is structurally modified to preferentially release nitric oxide in the liver. The references cited by the Examiner disclose compositions containing a nitric oxide donor. None of the references, however, discloses compositions that are structurally modified to preferentially release nitric oxide in the liver. Neither Adams et al., Papandreu et al., or Salzman et al. teach or suggest their disclosed compositions are capable of preferentially releasing nitric oxide in the liver. Therefore, none of the references cited by the Examiner teach every element of Applicant's claim.

The references cited by the Examiner do not anticipate Applicant's claim. None of the references teaches every element of Applicant's claim. Accordingly, Applicants respectfully request withdrawal of the rejection under § 102(e).

#### Obviousness

Claims 11-13 were rejected under 35 U.S.C. § 103(a) as unpatenable over Adams et al. and Papandreu et al. and Salzman et al. and Klokke-Bethke et al. and Veronesi et al. Applicant respectfully traverses the rejection.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. MPEP § 2142. Three criteria must be met by the Examiner to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. In re Vaack, 947 F.2d 488 (Fed. Cir. 1991). The Examiner has failed, in the least, to

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establish that the cited references, alone or in combination, teach or suggest all of the elements of Applicant's claims.

Applicant's claims are directed to a kit comprising a composition having a nitric oxide donor and/or nitric oxide agonist, wherein the composition is structurally modified to preferentially release nitric oxide in the liver, and instructions for administering the composition to ameliorate symptoms of insulin resistance. None of the references, alone or in combination, teaches every element of Applicant's claim.

As discussed above, the references cited by the Examiner disclose compositions containing a nitric oxide donor or nitric oxide agonist. None of the references, however, discloses compositions that are structurally modified to preferentially release nitric oxide in the liver. None of the references, alone or in combination, teach or suggest their disclosed compositions are capable of preferentially releasing nitric oxide in the liver. None of the references, alone or in combination, provide a motivation for structurally modifying compositions comprising a nitric oxide donor or agonist to preferentially release nitric oxide in the liver.

Citing *In re Ngai* and *In re Gulack*, the Examiner alleges the instructions for administering the compositions of the invention to ameliorate symptoms of insulin resistance does not further limit or defined the overall pharmaceutical compositions. Applicant does not agree.

In *Ngai* and *Gulack*, both the prior art and claimed invention contained instructional materials. In contrast, none of the references cited by the Examiner disclose formulating the compositions in a kit with instructional material. None of the cited references, alone or in combination, teach or suggest formulating the compositions into a kit with instructions for administering the compositions to treat insulin resistance. None of the references, alone or in combination, provide a motivation for formulating the claimed structurally modified compositions into a kit with instructions for administering the compositions to ameliorate symptoms of insulin resistance.

Based on the forgoing, Applicant submits the Examiner has failed to establish a *prima facie* case of obviousness. The cited references, alone or in combination, do not disclose all the elements of Applicant's claims. None of the references, alone or in combination, teach or suggest a composition comprising a nitric oxide donor and/or nitric oxide agonist, wherein the

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composition is structurally modified to preferentially release nitric oxide in the liver. None of the references, alone or in combination, teach or suggest formulating the claimed compositions into a kit with instructions for ameliorating symptoms of insulin resistance. Accordingly, withdrawal of the rejection under §103(a) is respectfully requested.

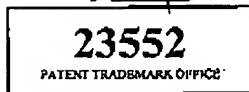
### Conclusion

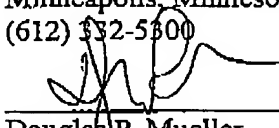
In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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